IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/804,348
Applicant : Stephen K. Harrel
Filed : March 19, 2004
TC/AU : 3723
Examiner : MORGAN, Eileen P.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 on October 1, 2004, by depositor Roger N. Chauza

Roger N. Chauza (Signature) OCT. 1, 2004 (Date)

Docket No. : HARR-24,972CO
Customer No. : 31782

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

DECLARATION UNDER 37 C.F.R. § 1.132

The purpose of this Declaration is to establish factual evidence as to why the Rosenberg patent reference (5,797,744) does not anticipate the various claims of the captioned application, and why one skilled in the art would not combine the teachings of the Rosenberg patent reference with the teachings of the Nash patent reference (4,283,175) to establish a prima facie case of obviousness.

1. I, STEPHEN K. HARREL, a resident of Dallas, Texas, 75229, am the inventor and Applicant of the subject matter claimed in the above-referenced patent application.

2. I am a graduate of Austin College in Sherman, Texas. In May of 1967, I received a Bachelors of Arts degree with a major in Biology and Chemistry. I received a Master of Arts degree from the University of North Texas in Microbiology and Biochemistry in August of 1968. I received a Doctor of Dental Surgery degree from Baylor College of Dentistry in May of 1972. I completed a residency in Periodontology at the University Of Oregon Health Science Center and was awarded a post doctoral certificate in Periodontology in June of 1974.

3. For 25 years, I have been an instructor in the Periodontal Residency program at Baylor College of Dentistry and I currently hold the position of Associate Professor within the Texas A and M University System (TAMUS). My duties within the above-noted periodontal residency program include the teaching of surgical techniques which involve the use of an ultrasonic scaler as well as the review of current scientific dental literature. Another portion of my teaching responsibilities is performing research in association with the Dental Hygiene department on clinical technique and infection control. Dental hygienists are the primary users of prophy cups and ultrasonic scalers. In most instances my research in conjunction with the Dental Hygiene faculty has involved the use of these instruments.

4. I am familiar with the process in applying for patents and receiving U.S. patents. The following patents issued to me as an inventor of the subject matter claimed therein:

a) U.S. Pat. No. 5,122,153 entitled "Tissue Removing Instrument."
b) U.S. Pat. No. 5,378,150 entitled "Methods and Apparatus for Controlling the Aerosol Envelope Generated by Ultrasonic Devices."
c) U.S. Pat. No. 5,547,376 entitled "Methods and Apparatus for Containing and Recovering Abrasive Powders From an Abrasive Polisher."
d) U.S. Pat. No. 5,901,930 entitled "Cord Strain Relief Device for Reducing Cumulative

Trauma Disorders."

5. I have received a number of international patents related to one or more of the above-referenced U.S. patents.

6. I have published the following papers:

a. Harrel, S.K., Nunn M.: Longitudinal comparison of the periodontal status of patients with moderate to severe periodontal disease receiving no treatment, non-surgical treatment and surgical treatment utilizing individual sites for analysis. J. Periodontol 2001,72:1509-1519.

b. Harrel, S.K. and Nunn, M.: The effect of occlusal discrepancies on periodontitis: II. Relationship of occlusal treatment to the progression periodontal disease. J. Periodontol 2001,72.

c. Nunn, M. and Harrel, S.K.: The effect of occlusal discrepancies on periodontitis: I. Relationship of initial occlusal discrepancies to initial clinical parameters. J. Periodontol. 2001,72.

d. Harrel, S.K. and Wright, M.: Treatment of periodontal destruction associated with a cemental tear using minimally invasive surgery. J. Periodontol. 2000.71.

e. Harrel, S.K., Nunn, M, Belling, C.M.: Long-term results of a minimally invasive surgical approach for bone grafting. J. Periodontol. 1999;70:1558-1563.

f. Harrel, S.K.: A minimally invasive surgical approach for periodontal regeneration: Surgical technique and observations. J. Periodontol. 1999;70:1547-1557.

g. Harrel, S.K., Barnes, J.B., Rivera-Hidalgo, F.: Aerosol reduction during air polishing. Quin. Int. 1999;30:623-628.

h. Rivera-Hidalgo, F, Barnes, J.B., Harrel, S.K.: Aerosol and splatter production by focused spray and standard ultrasonic insert. J. Periodontol 1999;70:473-477.

i. Harrel, S.K., Barnes, .J.B., Rivera-Hidalgo, F.: Aerosol and splatter contamination from the operative site during ultrasonic scaling. JADA 1998;129:1241-1249.

j. Harrel, S.K.: A minimally invasive surgical approach for bone grafting. Int. J. Periodont Rest Dent 1998;18:161-169.

k. Barnes, J.B., Harrel, S.K., Rivera-Hidalgo, F.: Blood contamination of the aerosols produced by the in vivo use of ultrasonic scalers. J. Periodontol 1998;69:434-438.

l. Harrel, S.K.: Use of an aerosol reduction device with ultrasonic scalers. Compendium of Continuing Education in Dentistry 1996,17:1185-1193.

m. Harrel, S.K. and Miller, C.M.: A technique for reducing aerosol during ultrasonic scaling. J. Practical Hyg. 1996,5:47-50.

n. Harrel, S.K., Barnes, J.B. and Rivera-Hidalgo F.: Reduction of aerosols produced by ultrasonic scalers. J. Periodontol 1996;67:28-32.

o. Harrel, S.K. and Rees, T.D.: Granulation tissue removal in routine and minimally invasive surgical procedures. Compendium of Continuing Education in Dentistry 1995;16:960-967.

p. Harrel, S.K.: Dental Aerosols: A growing concern. Biologic Therapies in Dentistry 2000;15:32-33.

q. Harrel, S.K.: Advances in Air Polishing Technique, Dental Connection. Vol , Issue 1, 1998.

r. Interaction of Bacteria with algae as a means to control algal blooms. Masters Thesis.

Many of these papers relate to the use of ultrasonic scalers or the various applications of a prophy cup.

7. I am thoroughly familiar with the operation of ultrasonic devices, as U.S. Pat. No. 5,378,150 identified above involved the use of a suction hood attached to an ultrasonic device. Attached hereto is a copy of my '150 patent. In my practice as a periodontal surgeon, I routinely use ultrasonic devices for surgical and non-surgical applications. I have used ultrasonic devices for 32 years, and thus am familiar with the structure and operation thereof. I have also supervised many assistants, dental hygiene students, and periodontal residents in the operation and use of ultrasonic devices.

8. In developing a prototype of the present invention, I used an ultrasonic device many times with many different tip configurations. As such, I am familiar with the mechanism in which ultrasonic devices operate, and action of the vibrating tips for removing buildup and roughness from workpiece surfaces.

9. I am thoroughly familiar with the structure and operation of prophy cups. In U.S. Pat. No. 5,547,376, a copy of which is attached hereto, there is described my use of a prophy cup with a dental abrasive polisher for containing the abrasive powders. The prophy cups of which I am aware that are sold commercially and used clinically are all constructed of a flexible rubber material so that they can flex and conform to the curvature of the tooth surface. I have experimented with many different types of prophy cups in developing my invention as disclosed in the '376 patent, all of which require a flexible body for effective clinical use.

10. I have licensed one or more of my patents to dental supply manufacturers who market dental devices both domestically and internationally, some of whom manufacture and market prophy cups. As a result, I have become well aware of the devices available in the dental area, including prophy cups and ultrasonic devices.

11. I read trade journals and am generally familiar with new and existing devices used in the dental field. In my position as a member of the Board of Trustees of the American Academy of Periodontology, I discuss with my colleagues new dental devices that are being marketed. Dental device market persons frequently contact me concerning existing and new dental devices. In view of this background, I, nor any of my colleagues I have spoken to, are aware of any use of a prophy cup with an ultrasonic device. I am also not aware of a prophy cup made of a rigid and non-pliable material. I am of the opinion that a prophy cup made of a rigid material would not work for its intended purpose, as it would not conform to the contour of a tooth surface.

12. The conventional use of a prophy cup of which I am aware, is with a handpiece that provides rotational movement of the prophy cup. The clinical technician places an abrasive

paste inside the cavity of the prophy cup, and applies the prophy cup against the tooth surface to be cleaned or polished. As the technician controls the handpiece to rotate the prophy cup, it is pressed against the tooth surface, which produces two results. First, the pressure between the prophy cup and the tooth surface dispenses the abrasive paste from the cavity of the prophy cup onto the tooth surface, much like a squeege. Secondly, the pressure causes the prophy cup to deform and conform to the shape of the tooth surface. All portions of the prophy cup touching the tooth surface are or become covered with the abrasive paste. As long as the rotating prophy cup is in contact with the tooth surface, it causes abrasion and corresponding removal of deposits and rough surfaces from the tooth.

13. At the request of counsel, I have studied the Office Action dated July 1, 2004, together with the patent references cited in the rejections of my claims. I have studied the Rosenberg patent reference (5,797,744) and the Nash patent reference (4,283,175), and I understand the teachings of both of the cited references.

14. As I understand the rejection of claims 3, 4, 6, 13 and 15, the Examiner has concluded that it would have been obvious to one skilled in the art to use the prophy cup disclosed in the Rosenberg reference with the ultrasonic device of the Nash reference to more thoroughly and efficiently abrade the tooth surface.

15. After studying the Rosenberg reference, I conclude that it is substantially similar to the prophy cups which I have used and am familiar, except the prophy cup of the Rosenberg patent has a cavity configuration with annular ridges, 32A, 32B and 32C and microcellular pores 30. The prophy cups that I have used and have been used by persons under my supervision, have a web design in the cavity to hold the abrasive paste.

16. I have attached hereto a prophy cup (attached to a contra angle) which is conventionally used with handpieces to remove deposits from teeth and otherwise polish tooth

surfaces.

17. As one skilled in the art of using both ultrasonic devices and prophy cups, I am of the opinion and conclusion that a prophy cup would not function to clean teeth if used with an ultrasonic device. The operation of an ultrasonic device depends on very high frequencies for mechanically vibrating a metal tip attached thereto. The magnitude of the vibrations are small, but at a high frequency, so that when the metallic vibrating tip engages the rough deposits on the tooth surface, the tip effectively "breaks" the rough deposits and removes the same from the tooth surface. Because of the differences in the modulus of elasticity between the deposits and the tooth itself, the deposits, and not the tooth, are fractured and broken. The small vibrations generated by the internal "pile" of the ultrasonic device must be transferred to the tip of the device to remove plaque and calculus from the tooth surface. In transferring the ultrasonic vibrations from the pile to the tip, the tip must be rigid and not pliable. In my opinion, if an elastomeric prophy cup were to be attached to the tip of an ultrasonic device, or otherwise driven by an ultrasonic device, the vibrations would be absorbed by the flexible material of the prophy cup and not felt between the tooth surface and the prophy cup.

18. I draw the foregoing conclusion because the Rosenberg patent reference states at column 2, lines 47-52, the following:

> The body 10 is formed of a solid elastomeric material, preferably polyisoprene having a durometer value of 55-75, so that the polishing portion is elastically flexible in response to being pressed against a tooth, to enable the front surface 18 to flex and generally conform to a contour of the tooth.

19. As one skilled in this field, I am of the opinion and conclusion that the prophy cup disclosed in the Rosenberg reference would not be effective to clean teeth if used in conjunction with the ultrasonic device of the Nash reference. It is also my opinion and conclusion that it would not have been obvious to one skilled in the art at the time my invention was made to combine an elastomeric prophy cup with an ultrasonic device to clean or polish teeth.

20. In the Office Action, a rejection of the claims is based on the conclusion that the sharp edges of the Nash ultrasonic scaler could be incorporated into the Rosenberg elastomeric prophy cup. I am not able to visualize how the sharp edges of the Nash scaler could be incorporated into a pliabale prophy cup. Since the prophy cup (with abrasive paste) is designed to provide an abrasion action when rotated, without damaging hard or soft tissue, I believe that the use of rotating sharp metallic edges would severely abrade and damage tooth and gingival tissues. In my opinion, the incorporation of a sharp metallic edge into a prophy cup would be too destructive to hard and soft tissues for any practical use.

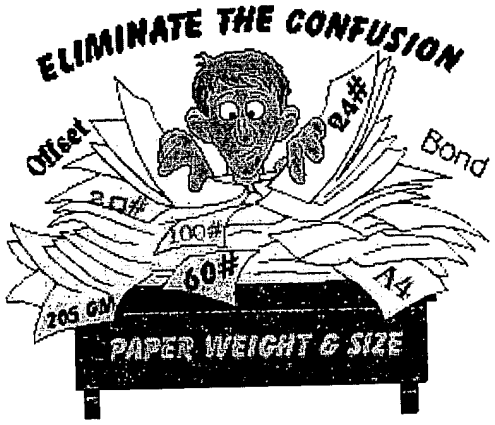
21. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issue thereon.

Respectfully submitted,

Stephen K. Harrel, D.D.S.

Date: 9.30.04

Let's End the Confusion



In an effort to help *eliminate the "Paper Weight" confusion problem,*
we have compiled the comprehensive table listed below.
Now you can compare various types of paper and their "Equivalent Weights.'

Definitions:

- ***Basis Weight***
  The basis weight of a paper is the designated fixed weight of 500 sheet
  measured in pounds, in that paper's basic sheet size.
  It is important to note that the "basic sheet size" is not the same
  for all types of paper.
- ***Caliper***
  Caliper refers to the thickness of a sheet of paper expressed
  in thousandth of an inch. This measurement is taken with a micro mete
  Normally, paper caliper should not have more than a + or - 5% varianc
  within a sheet. Generally, the relation between caliper and basis weight

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the greater the caliper (the thicker the paper), the greater the paper weig

- ***Equivalent Weight***
  While different paper types have different basic sizes, papers can still be compared by using equivalent weight.

Basis Weight ("Category") Table

Type Paper	Basic Size - 500 Sheets
"Bond" Ledger Mimeo Duplicator Rag Paper	17" x 22"
"Offset" Book Text Coated Paper	25" x 38"
"Cover"	20" x 26"
"Tag Stock"	24" x 36"
"Index"	25-1/2" x 30-1/2"

The Values in the table below are intended to serve as a guide only. They *should not be used as specifications* because there are variances within the same basis weight due to other characteristics of the papers. Similar weight papers may vary between different paper manufacturers.

	Bond	Offset	Cover	Tag	Index	Points	*Caliper (inches)	millimeters	M (grams
Equivalent	16	41	22	37	33	3.2	.0032	0.081	60.15 g
Weight	18	45	24	41	37	3.6	.0036	0.092	66.61 g
	20	50	27	45	41	3.8	.0038	0.097	74.01 g
	24	60	32	55	49	4.8	.0048	0.12	88.81 g
	28	70	38	64	57	5.8	.0058	0.147	103.61
	29	73	40	62	60	6	.0060	0.152	109.11
	31	81	43	73	66	6.1	.0061	0.155	118.42
	35	90	48	80	74	6.2	.0062	0.157	131.68
	36	90	50	82	75	6.8	.0068	0.173	135.45
	39	100	54	91	81	7.2	.0072	0.183	148.02
	40	100	56	93	83	7.3	.0073	0.185	150.5 g
	43	110	60	100	90	7.4	.0074	0.188	161.78
	44	110	61	102	92	7.6	.0076	0.193	165.55

						MM	
47	120	65	108 97	8	.0078	0.198	176.83
53	135	74	122 110	9	.0085	0.216	199.41
54	137	75	125 113	9	.009	0.229	203.17
58	146	80	134 120	9.5	.0092	0.234	218.22
65	165	90	150 135	10	.0095	0.241	244.56
67	170	93	156 140	10.5	.010	0.25	252.08
72	183	100	166 150	11	.011	0.289	270.9 g
76	192	105	175 158	13	.013	0.33	285.95
82	208	114	189 170	14	.014	0.356	308.52
87	220	120	200 180	15	.015	0.38	312 gs
105	267	146	244 220	18	.0175	0.445	385.06

* Normal *paper manufacturing tolerance* within a paper production run is + or - 5% to 7% caliper

The darker colored boxes above,
represent the "most common paper weights" for that category.


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International Metric Paper Sizes - ISO Standard

SIZE	WIDTH (mm)	HEIGHT (mm)	WIDTH (in.)	HEIGHT(i
A0	841 mm	1,189 mm	33.11 in.	46.81 in.
A1	594 mm	841 mm	23.39 in.	33.11 in.
A2	420 mm	594 mm	16.54 in.	23.39 in.
A3	**297 mm**	**420 mm**	**11.69 in.**	**16.54 in.**
A4	**210 mm**	**297 mm**	**8.27 in.**	**11.69 in.**
A5	148 mm	210 mm	5.83 in.	8.27 in.
A6	105 mm	148 mm	4.13 in.	5.83 in.
A7	74 mm	105 mm	2.91 in.	4.13 in.
B0	1,028 mm	1,456 mm	40.48 in.	57.32 in.
B1	728 mm	1,028 mm	28.66 in.	40.48 in.
B2	514 mm	728 mm	20.24 in.	28.66

B3	364 mm	514 mm	14.33 in.	20.24 in.
B4	257 mm	364 mm	10.12 in.	14.33 in.
B5	182 mm	257 mm	7.17 in.	10.12 in.
B6	128 mm	182 mm	5.04 in.	7.17 in.

HELPFUL GUIDELINES for PAPER USAGE

- Prior to use, paper should be allowed to acclimate at least 48 Hours in the environment in which it will be used. Optimum storage facility would retain temperatures between 70-80 deg with 50% relative humidity.
- Before loading paper, fan the sheets on all four sides. This creates a small layer of air between the sheets which should help printer feeding mechanisms.
- Do Not Stack Materials such as Designer Gold, Designer Silver, Super Color Gloss, Super Color Photo, Super Color Photo Cards, Super Color Shrink. Feed into printer one sheet at a time.
- Load Materials according to the instructions in the printer owner's manual. Recommended feeding is generally to use the manual feed tray, or the s path through the printer.
- Upon Completion, the unused material should be stored in a closed package, re-sealed and stored flat.

Glossary of Paper Terms

- **Acid Free Paper**
Paper manufactured to a neutral pH reading (7).
Used for fine art prints, limited edition printing, scrapbooking

- **Antique Finish**
Random surface quality created by "felts" in the manufacturing process

- **Brightness**
Light reflecting property of paper when measured under a specially calibrated blue light.

- **Basis Weight**
The weight of one ream of paper (500 sheets) when cut to the industry standard for that specific grade of paper.

- **Bristols**
Solid or laminated heavy-weight printing paper made to a thickness of .006" or higher. Bristols are often used for printed items that require repeated handling.

- **Bulk**
The thickness of paper when compared to its weight. A high bulk paper is thicker but less compact than a low-bulk paper of the same weight and size.

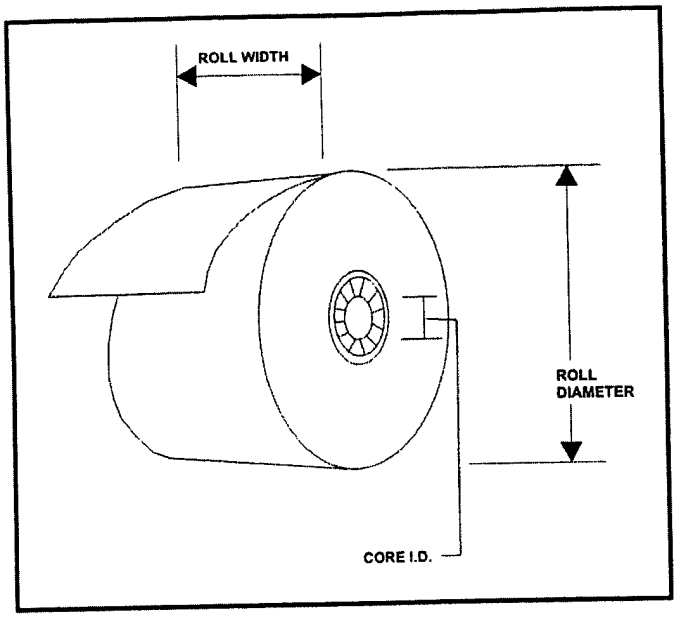
- **Calendering**
Part of the paper manufacturing process where the paper "web" passes between polished metal rolls. This increases the paper's smoothness and provides a uniform thickness (caliper).

Thermal Paper ~ Shelf Life - Storage
Thermal Paper Information as supplied to us by Appleton Papers.

Links you should know

- Calculator
- Language Translator
- Patent Search
- Spell Check
- Trade Mark Search
- Unit converter

Additional Definitions of Standard Paper Terminology and Abbreviation



Bond	Uncoated "plain" paper - free from impurities. Also referred to as "free sheet."
Recycled	Paper manufactured from the waste paper stream. All Micro Format recycled products contain a minim 100% recycled material including 40% post consum
Waste Paper Stream	Waste paper created during the paper manufacturing
Post Consumer Waste	Processed Paper that has been re-used in manufactur paper products
Carbonless	Paper coated with special encapsulated chemicals th a duplicate copy without the use of carbon paper
Thermal	A paper coated with special chemicals that produce an image when heat is applied
Groundwood	A low cost paper that contains unprocessed wood fit
Symbol "#"	"pound" - used to describe paper weight Click for additional information on **PAPER WEIGI**
Symbol "M"	Meter - 1 meter=39.37 inches
Symbol "mm"	Millimeter - 1 inch=25.4 millimeters
Symbol "sc"	Self Contained Paper paper that can be imaged in a printer without the use
Symbol "cb"	Coated Back - Carbonless Paper (part 1)
Symbol "cfb"	Coated Front and Back - Carbonless Paper internal part in a multipul part form
Symbol "cf"	Coated Front - Carbonless Paper (last part in set)
	Self Contained sheet with carbonless coating on bacl

Symbol "sccb"	normally used as part one in a multi part set in an im using no ribbon
Symbol "sccb/cf"	Carbonless set - Self Contained Coated Back Sheet I Coated Front Sheet Part 2
Symbol "w"	Paper Color - White
Symbol "c"	Paper Color - Canary
Symbol "p"	Paper Color - Pink
Symbol "g"	Paper Color - Green
Symbol "b"	Paper Color - Blue

ADDITIONAL COVERSION TABLES

How to Convert to Metric

Length and Distance

When you know	Multiply by	To Find
inches	2.54	centimeters
feet	30.480	centimeters
miles	1.609	kilometers
centimeters	0.394	inches
meters	1.094	yards
kilometers	0.621	miles

Weight

When you know	Multiply by	To Find
pounds	0.454	kilograms
tons	0.907	metric tons
kilograms	2.205	pounds
metric tons	1.202	tons

Temperature

When you know	Do This	To Find
degrees Fahrenheit	Subtract 32 multiply by 5/9	degrees Celsius
degrees Celsius	Multiply by 9/5 then add 32	degrees Fahrenheit

Surface or Area

When you know	Multiply by	To Find
square feet	0.093	square meters
square miles	2.590	square kilometers
square centimeters	0.155	square inches
square kilometers	0.386	square miles

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1/64
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